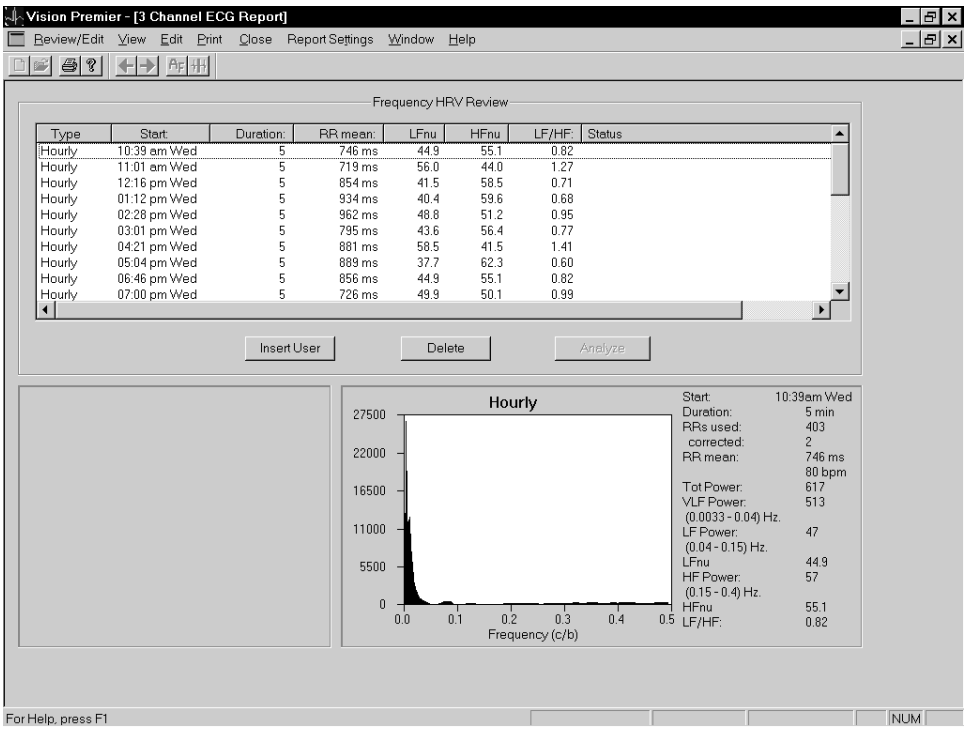
Operating Instructions



Vision™ Series
HRV Software Option

Operating Instructions Part No. 086558-HR
Revision: 0103

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Chapter 1 *Introduction to HRV*

Overview

The HRV software module uses previously acquired ECG data. The data will have been previously analyzed utilizing the Burdick, Inc. Arrhythmia detection algorithms included in the Vision™ Series Holter Analysis Systems. This algorithm builds a QRS beat annotation file, which contains the fiducial point and the classification of each QRS complex. The analysis software supports a minimum 5-msec fiducial resolution. The primary data input to the HRV module is the QRS beat annotation file. The Vision™ Series systems have data viewers and editors, which enable you to review the raw ECG data in conjunction with the resultant QRS annotation file data. You can manually edit this data to override the automatic classification performed by the arrhythmia detection module. Any editing of the ECG report will automatically force a recompile of HRV results upon accessing HRV information.

An HRV Time Domain Summary Report page and a Frequency Domain Summary Report page are printed along with the Final Report. After you have finished editing Holter data, review and edit the HRV report data as desired. You can select the HRV option from Review/Edit menu.

Intended Use

NOTICE: Computer assisted interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

The Heart Rate Variability (HRV) module is an optional software feature which may be added to Vision™ Series Holter Analysis Systems.

NOTE: In this manual, THRV describes Time Domain, SHRV describes Frequency Domain and HRV describes both.

Installing the Program

NOTE: The Vision Series Setup Guide contains additional information, including requirements, for installing and removing software and licenses.

Install License

NOTE: If you are installing the license onto a computer with Windows 95 or Windows 98 Second Edition, then you must follow the instructions under "Configure Environment Variables" on pg. 1-3 prior to installing the license.

1. Insert the license CD into the CDR drive.
2. Click on Start in the lower left corner on the screen.
3. Click Run.
4. Click [Browse] to locate **X:\install_license.bat** (where **X:** is the drive designator for the CDR drive).
5. Click install_license.bat.
6. Click [Open].
7. Click [OK]. The License software will install onto your system. When the License installation is complete, the system returns to the Windows® desktop.
8. Press the eject button on the CDR drive. The Adaptec DirectCD Wizard appears.
9. Ensure that the Leave the disc as it is… option is selected.

   CAUTION: Selecting any other option may result in damage to the license CD.

10. Click [Finish] and remove the CD disk from the CDR drive.

Remove License

Follow the instructions under "Install License" above. For step 4 and step 5, locate and select the file **remove_license.bat.**

Configure Environment Variables

If you are installing onto a computer with Windows 95 or Windows 98 Second Edition operating system, then complete the following steps below before installing the license.

1. Click **Start** in the lower left corner on the screen.
2. Click **Run**.
3. Type the following: **edit c:\config.sys**
4. Click **[OK]**. A text editor displays the contents of the config.sys file.
5. Scroll to the end of the file. If the following text does not appear, add it to the end of the file:

   SHELL=C:\WINDOWS\COMMAND.COM C:\WINDOWS /P /E:2048
6. Click **File** and select **Save**.
7. Click **File** and select **Exit**.
8. Restart the computer.

Chapter 2 *Description of Spectral HRV Analysis*

Description

The autonomic nervous system controls the heart. Heart rate is controlled by a combination of parasympathetic and sympathetic nervous system influences. The heart rate data can be analyzed in the frequency domain to determine the frequency components of the heart rate. The parasympathetic/respiratory activity creates a high frequency component (0.22-0.28 Hz) of the spectrum heart rate data. The sympathetic nervous system in conjunction with the parasympathetic nervous system create a low frequency component (0.06-0.12 Hz).

Research indicates that decreased heart rate variability is an indicator of increased risk for sudden cardiac death. Decreased heart rate variability is also an indicator of increased risk of cardiac death after acute myocardial infarction. The relative interaction between the parasympathetic activity (high frequency SHRV components) and sympathetic activity (low frequency SHRV components) can be graphically displayed using the SHRV power spectral analysis technique.

The SHRV software performs frequency domain analysis utilizing Fast Fourier Transform (FFT) and autoregressive (AR) modeling frequency domain approaches.

Spectral Analysis Processing Functions

The SHRV module calculates the power spectra utilizing FFT and/or AR techniques for the specified data intervals utilizing the R-R data contained in the QRS annotation input file.

The data is first processed by a qualification algorithm that finds the data interval with the least amount of artifact:

Example

The operator selects a minimum time segment of 5 minutes and then selects a segment to be extracted from within a 60-minute region. The qualification algorithm searches the entire 60 minutes to find the best 5-minute interval where no correction is needed. If no such interval is found, additional logic evaluates the region to find an interval requiring a minimum number of corrections.

The data to be processed can be a resampled time series or an interval tachogram. If the data-correction mode of operation is enabled, anomalies (such as PVCs, SVEs and some types of artifact) are corrected with a spline matching technique. The data correction algorithm will not correct across successive VE or SVE, or if single VE or SVE occur within 3 beats to each other. For AR analysis, the input R-R data can be filtered using operator-selected filter types. Smoothing of the output data should be per the selection in the

parameter file. If the input data is resampled, the output data is generally in units of MS^2/Hz as a function of frequency in Hertz. If the input data is left as an interval tachogram, the output data is a function of cycles per beat (CPB) in units of MS^2/CPB.

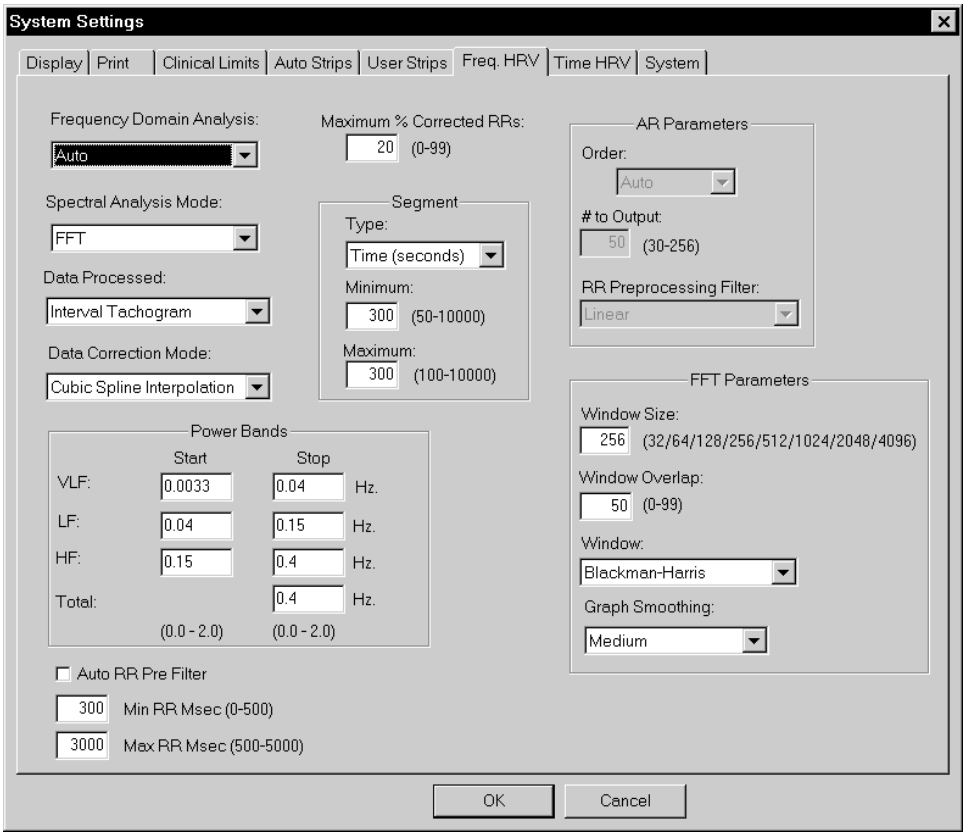
Changing HRV Configuration Parameters

The Frequency Domain analysis can be configured for the following modes of operation. The first mode OFF, allows SHRV to be turned off. The second mode of operation, Automatic mode, will automatically pick time segments and allow you to add specific times. The third mode, Manual mode, only allows you to add specific times. The automatic report for SHRV consists of a single page summary report which includes the hourly results. The user added aspect allows you to manually select up to 25 individual time segments where each epoch could be printed out in individual mini reports. You can review on the display each individual epoch whether automatic or manual. Additionally, individual reports can be printed out.

The analysis parameters for performing a spectral computation are adjustable.

To change HRV Configuration parameters start the Vision™ Series application , then:

1. Click on System Settings in the menu bar.
2. Click on the Freq. HRV tab.
3. Change the configuration parameters as required.



Field	Options	Description
Frequency Domain Analysis	Off (Default) Auto Manual	Enables the SHRV analysis. NOTE: The Frequency Domain Analysis option can only be changed if the SHVR software is installed on the system. SHRV software is used for research purposes only.
Spectral Analysis Mode	Autoregression FFT (Default)	This parameter determines the spectral analysis technique to be performed.
Data Processed	Interval Tachogram (Default) Resampled Time Series	This parameter determines the data source. If Interval Tachogram is selected, the direct R-R event series is used and the output is in ms^2/CPB. If Resampled Time Series is selected, for each second of time, a linear interpolation is performed between the closest previous occurrence and the closest subsequent one. The output is in BPM^2/Hz.
Data Correction Mode	Cubic Spline Interpolation (Default) None	This parameter determines if R-R intervals should be corrected in areas of artifact, noise, PVCs and other non-normal R-R areas. The Cubic Spline Interpolation technique replaces a couple of missing R-R intervals by estimating a best cubic line fit between the two preceding and two subsequent good R-Rs.
Power Bands		
The Power is calculated for each band. Defaults are listed below. NOTE: VLF information will not be displayed if duration of segment is less than 15 minutes. VLF, LF, Total Power limits are adjustable with a range of 0.0 <--> 2.0Hz.		
		Range, Cycles/Min, Cycle/Sec
	VLF (Very Low Frequency)	0.0033-0.04 Hz, 0.3 to 2.4, 303 to 25
	LF (Low Frequency)	0.04-0.15 Hz, 2.4 to 9, 25 to 6.6
	HF (High Frequency)	0.15-0.40 Hz, 9 to 24, 6.6 to 2.5
	Total Power upper limit	0.40 Hz, <2.5

Field	Options	Description
R-R Filters		
Min/Max Section The Min/Max RR sets the threshold for rejecting beats based on the RR interval.		
Auto R-R Pre-Filter	Enable Disable (Default)	Rejects all normal R-R that are less than 0.5 or greater than 1.5 of the previous accepted 8-beat NN running average.
Minimum R-R (Msec)	300ms (Default)	Ignores R-R intervals which are less than the threshold. Range (0 - 500ms)
Maximum R-R (Msec)	3000ms (Default)	Ignores R-R intervals which are greater than the threshold. Range (500 - 3000ms)
Segment Type		
	Time (sec) (Default) Beats	The segment type in combination with the segment size is used to define the min/max length of the R-R time series to process.
Segment Size		
	Minimum	50 to 10,000 (default = 300)
	Maximum	100 to 10,000 (default = 300)
Maximum% Corrected R-Rs	0 to 99 (Default = 20)	The maximum percentage of correction allowed to allow the segment to be processed.
AR Parameters		
With this technique, the power spectral density is calculated after modeling the tachogram (resampled or not) to an autoregressive method. The tachogram is assumed to be a single realization of a stationary random process of autoregressive type, i.e. the value at the output of the process at a given time (a single R-R interval), is a function of the outputs of the process at p previous (AR) time instances (where p is the order of the model) plus the synchronous value of an input white noise (flat or constant power) process. When this modeling is possible (which is NOT always the case), the spectral density can be determined on the basis of the parameters of the model (i.e. the weighting factors of the previous R-R intervals in the regression). In particular, by considering the transfer function of the model, the spectrum can be determined on the basis of the poles of the system. These poles can be real or in complex-conjugate pairs, and they respectively imply a frequency component at zero or Nyquist frequency or at a frequency determined by the phase of the complex-conjugate couple. The estimation of the model parameters is performed with the Levinson Durbin Algorithm. The whiteness test is performed by the Anderson test. Once the Autocorrelation function of the error prediction sequence has been calculated, the Anderson test checks how many times the estimated function overcomes a threshold (if “too many times” the test is not verified).		

Field	Options	Description
AR Order	Auto (0) (Default) 7 through 20	This parameter determines the frequency resolution of the AR modeling technique. High values for this parameter will provide better frequency resolution but can cause false frequency components to be generated. A parameter of 0 causes the AR analysis to try to automatically determine the best model. Setting the AR order to a value in the range of 7 to 20 will override automatic selection and force the selected order. Some AR models, usually with small number of orders, may not generate any components that have a central frequency in the desired band and in this event, the total power in the desired band is reported, similar to standard FFT analysis. In the event there are multiple components with a central frequency in the desired band, the power reported will be the sum of all the bands. To indicate an instance where no central frequency was found in a band, an asterisk (*) is displayed next to the reported power.
# to Output	30 to 256 (Default = 50)	This parameter defines the output resolution of the AR results.
R-R Preprocessing Filter	None Linear (Default) Exponential	A DC filter is always used to remove the mean of the R-R data. This prevents the DC component from obscuring the higher frequency components contained in the data. Additionally, these optional filters can be applied to the R-R interval data before the AR analysis is performed. The linear filter first finds the regression line (y = interc + slope x i), then subtracts the line. The exponential filter, first finds the fitting exponential, then subtracts this exponential.
FFT Parameters		
The power spectral density is calculated with the technique of average Periodogram on overlapping windowed segments (Nuttal and Carter approach). The basic idea of this classical method is that the classical Periodogram (by itself an estimate of the power spectral density) is an unbiased but (unfortunately) inconsistent estimator. Consistency is an essential characteristic of all estimators and it refers to the variance of the estimator itself to decrease with the increase of data used for the estimation. As stated, this is not the case for the Periodogram and that is why the averaged Periodogram is applied. The variance is then inversely proportional to the number of estimates used and goes to zero for an infinite number of estimates. The “overlapping” feature is not a requirement for the estimation but simply a way to increase the number of estimates given a fixed-length tachogram and a specified FFT size. NOTE: the R-R pre-filter is not applied in the FFT mode.		

Field	Options	Description
Window Size	32 64 128 256 (Default) 512 1024 2048 4096	This controls the size of the window.
Window Overlap	0 to 99	This parameter determines the amount of overlap of adjacent windows when the average power spectrum is calculated. The values represents the percentage of window overlap that is used during the spectral averaging operation mode. It can be used to minimize data distortions caused by the non-uniform amplitudes when some windowing functions are applied to the R-R interval data. A value of 50 should generally be used with the Blackman-Harris and Hanning windows. The rectangular window would generally use an overlap of 0. These values will minimize amplitude variations associated with the windowing and averaging processes.
Window	Blackman-Harris (Default) Rectangular Hanning Hamming	This parameter is used to determine which type of window is used during the FFT spectral analysis. These windows control the trade-off between spectral resolution and side lobe leakage. The default window is the Blackman-Harris which provides minimal spectral leakage while providing good spectral resolution.
Graph Smoothing	None Low Medium (Default) High	This parameter is used to smooth FFT graphical results.

Chapter 3 *Description of Time Domain Analysis*

Description

The THRV report is updated each time the data is edited. All individual results such as procedure, day, night and all individual segments are treated as independent analysis periods.

For HRV analysis, all normal beats within the entire Holter analysis period are analyzed. Only normal beats are analyzed.

Each time segment window displays a series of measurements described below.

NNs	Number of normal R-R intervals
NN (mean)	Mean of the normal R-R intervals between two consecutive normal sinus beats (in milliseconds).
SDNN	Standard deviation of all normal R-R intervals in the time segment.
SDANN	Standard deviation of the mean of all 5-minute segments of normal R-R intervals in the current time segment (in milliseconds).
SDANNIDX	Mean of the standard deviations of all normal R-R intervals for all 5-minute segments of the selected time segment (in milliseconds).
NNNs	Number of adjacent normal intervals in the selected time segment.
rMSSD	Root mean square of the successive differences; square root of the mean of the sum of the squares of differences between the adjacent normal R-R intervals over the selected time segment (in milliseconds).
pNN>50	Percent of differences between adjacent normal R-R intervals that are greater than 50 msec computed over the selected time segment.

Changing HRV Configuration Parameters

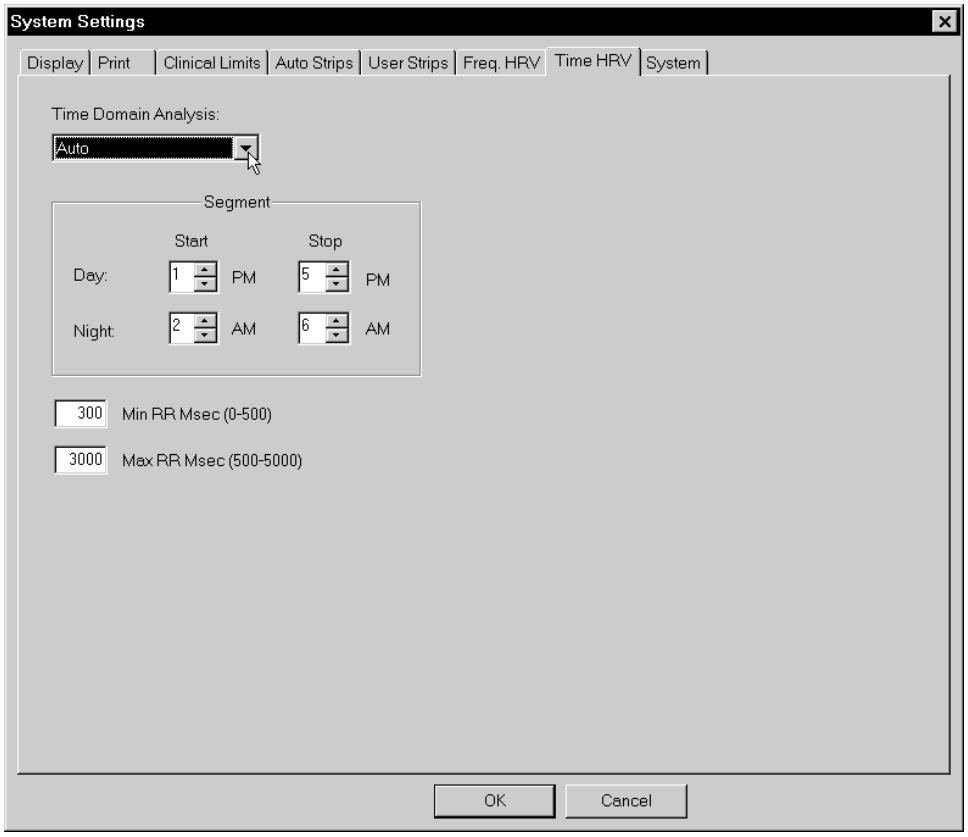
The Time Domain analysis can be configured for the following modes of operation. The first mode OFF, allows THRV to be turned off. The second mode of operation, Automatic mode, will automatically pick time segments and allow you to add specific times. The third mode, Manual mode, only allows you to add specific times. The automatic report for THRV consist of a single page summary report which includes the procedure results, day/night results

and hourly results. A day/night segment has been added to allow evaluation of the HRV during sleep and active conditions. The user added aspect, allows you to manually select up to 25 individual time segments where each epoch could be printed out in individual mini reports. You can review on the display each individual epoch whether automatic or manual. Additionally, individual reports can be printed out.

The analysis parameters for performing a time domain are adjustable.

To change HRV Configuration parameters start the Vision™ Series application , then:

1. Click on System Settings in the menu bar.
2. Click on the Time HRV tab.
3. Change the configuration parameters as required.



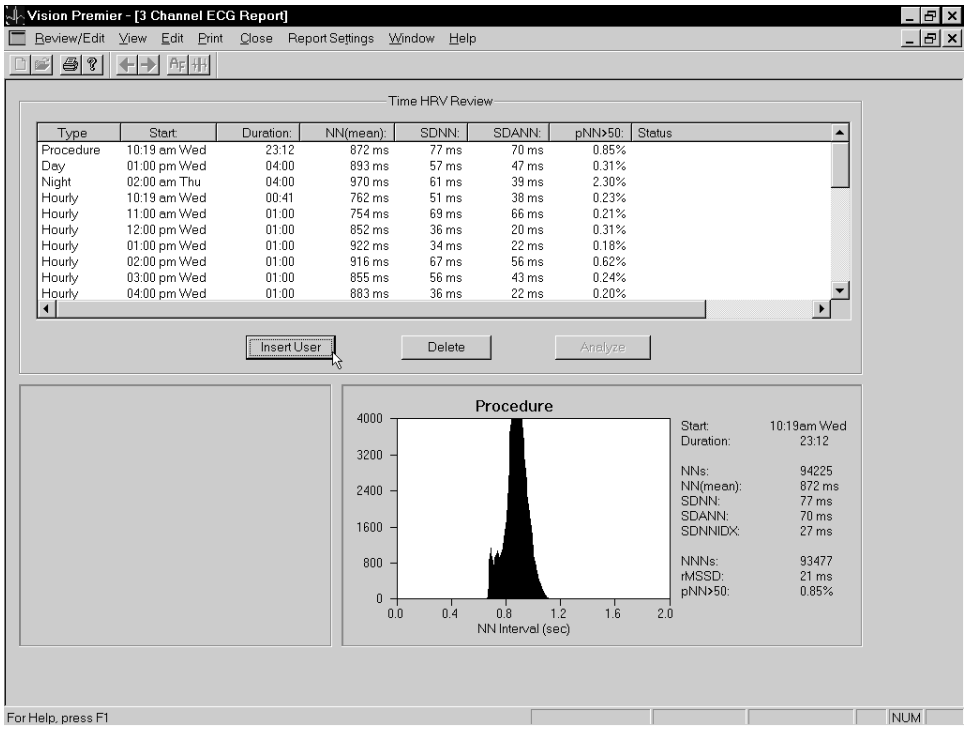
NOTE: Min RR ignores R-R intervals which are less than the threshold (range 0 - 500ms). Max RR ignores R-R intervals which are greater than the threshold (range 500 - 3000ms).

Chapter 4 *Review Time Domain Report*

THRV View

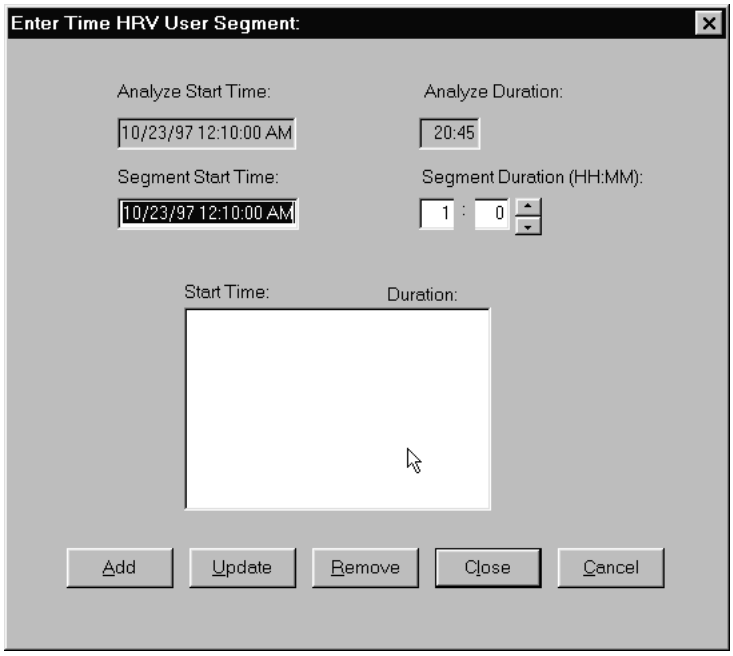
To review the Time Domain HRV select HRV under the Review/Edit menu. The available operations will be to Insert User, Delete and Analyze HRV segments. The top section of the view displays a list of HRV segments where several columns of information are displayed. Selecting an entry in the list will display that HRV segment's results in the lower right portion of the display.

Below is the current Time Domain View.



Insert THRV Specific Times

Selecting the Insert User button, will allow you to enter up 25 individual time regions. After an entry is inserted, it will indicate a status of "Not Analyzed". Closing or printing the opened report will force all Un-Analyzed HRV segments to be analyzed.

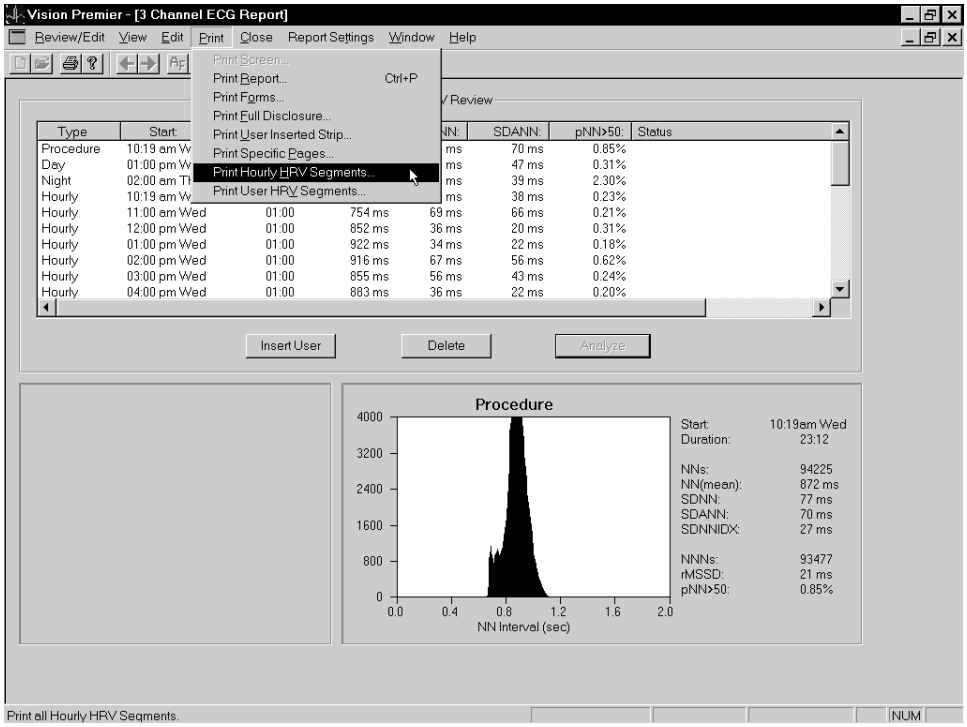


Delete HRV Segment

Selecting the Delete button will delete all highlighted HRV segments.

Print HRV Report

The following pages are available to be printed at any time through the Print menu as part of the Print Specific Pages dialog. The pull down menu shown below illustrates the print options.



Print Time Domain Summary

Prints a summary page consisting of Procedure, day and night segment graphs and tabulated automatic hourly segments.

When viewing HRV information, two new print menu items appear under the Print Menu. These items will only be active if Time Domain hourly or user segments exist.

Print Hourly HRV Segments

Prints all automatic hourly segments, in a condensed graph form.

Print User HRV Segments

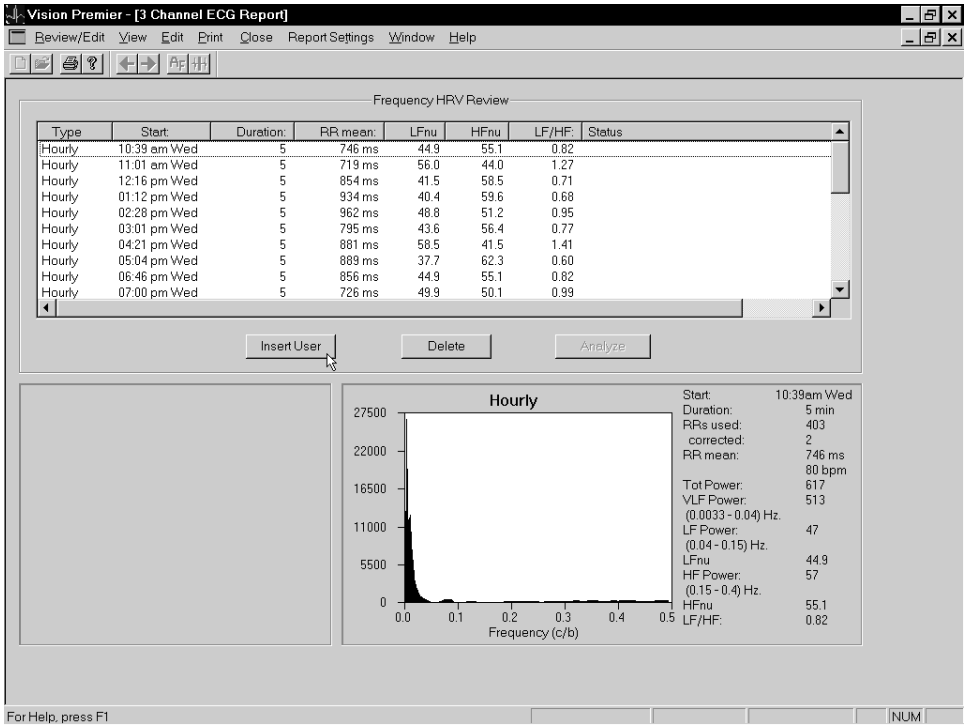
Prints all user-added segments in a condensed graph form.

Chapter 5 *Review Frequency Domain Report*

SHRV Viewer

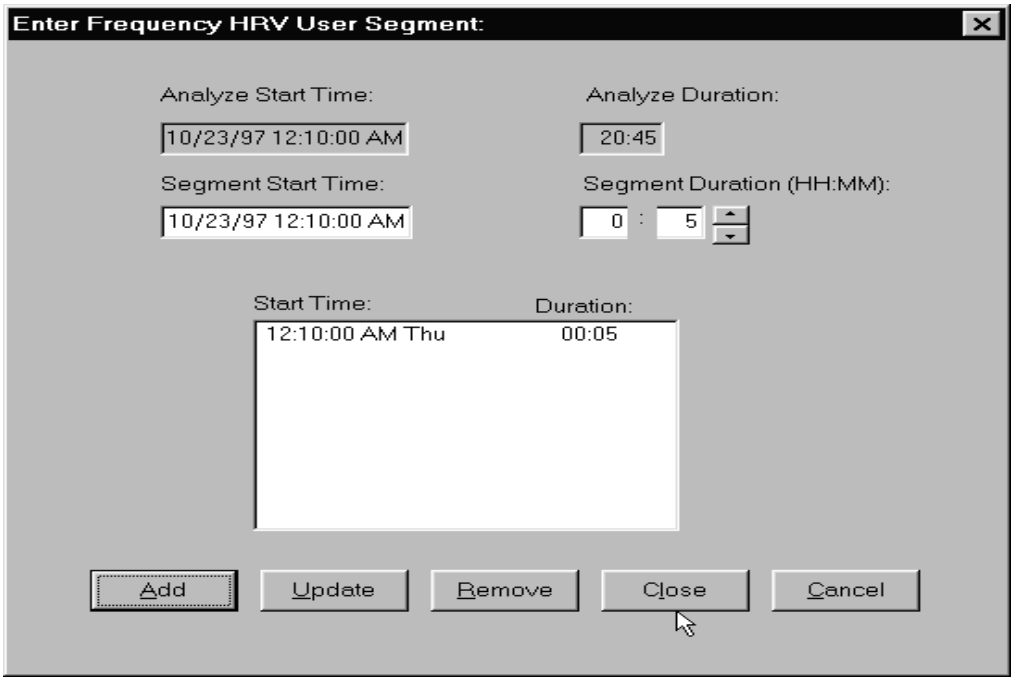
To review Spectral Domain SHRV, select HRV from the Review/Edit menu. The available operations will be to Insert User, Delete and Analyze HRV segments. The top section of the view displays a list of HRV segments where several columns of information are displayed. Selecting an entry in the list will display that HRV segment's results in the lower right portion of the display.

Below is the current Frequency Domain View.



Insert HRV Specific Times

Selecting the Insert User button, will allow you to enter up 25 individual time regions. After an entry is inserted it will indicate a status of "Not Analyzed". Closing or printing the current report will force all Un-Analyzed HRV segments to be analyzed.

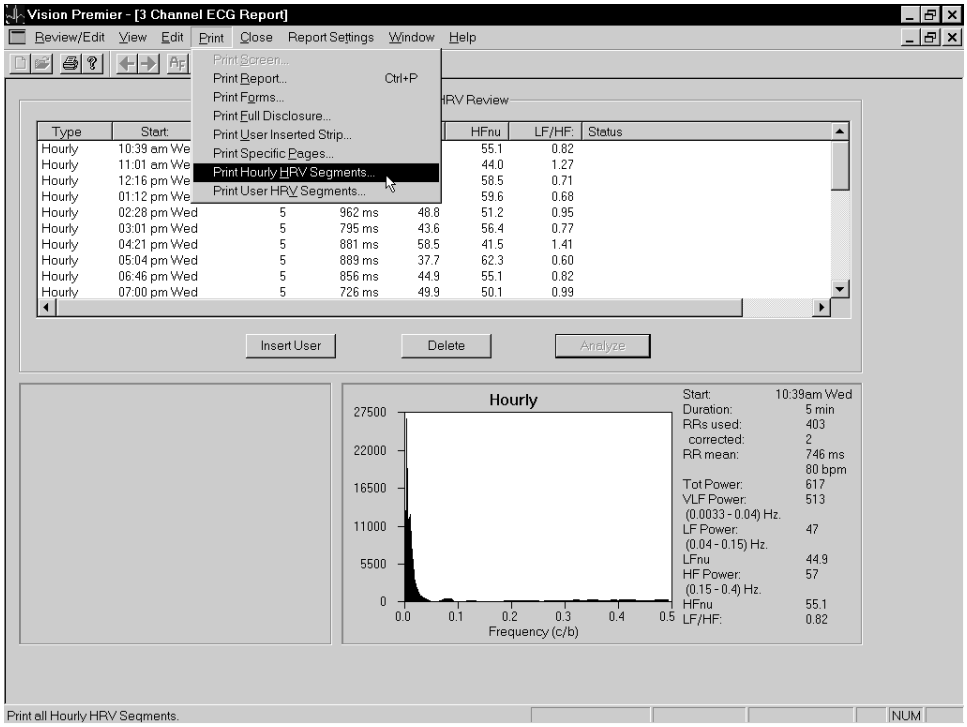


Delete HRV Segment

Selecting Delete will delete any highlighted HRV segments.

Print HRV Segment

The following pages are available to be printed at any time through the Print menu as part of the Print Specific Pages dialog. The pull down menu illustrates the print options available while viewing HRV.



Print Frequency Domain Summary

Prints a summary page consisting of graphs for the maximum and minimum LF/HF ratio segment, plus tabulated automatic hourly measurements.

When viewing HRV information, two new print menu items appear under the Print Menu. These items will only be active if Frequency Domain hourly or user segments exist.

Print Hourly HRV Segments

Prints all automatic hourly segments in a condensed graph form.

Print User HRV Segments

Prints all user-added segments in a condensed graph form.

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